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LETTER TO ALL RESPIRATOR MANUFACTURERS

Subject: Clarification of Supplier and Subcontractor Relationships

Background

National Institute for Occupational Safety and Health (NIOSH or the Institute) approval holders have established relationships with suppliers and subcontractors who are manufacturing components or subassemblies for approved respirator configurations. A growing number of approval holders wish to ship NIOSH-approved respirators directly from a subcontractor to distribution centers or customers, and replacement parts directly to a repair center. The Institute has identified two possible approval holder relationships with suppliers and subcontractors. Listed below are the responsibilities and requirements NIOSH has established for these relationships.

Definitions

Approval Holder: The party of record to whom certificates of approval have been issued. The approval holder maintains responsibility for, and control of, product design, performance, configuration management, manufacture, quality, and support.

Supplier: A supplier produces components or subassemblies under their own quality system for delivery to the approval holder. The approval holder confirms the acceptability of incoming goods by accepting a Certificate of Compliance and inspecting incoming goods to ensure compliance with all product design, performance, and quality assurance criteria (drawings and engineering control). The approval holder releases the product for distribution and sale.

Subcontractor: The approval holder may authorize a subcontractor to release NIOSH-approved respirators directly from their facility for distribution and sale, or to release components and subassemblies directly to an authorized repair center. The approval holder maintains responsibility for, and control of, product design, performance, configuration management, manufacture, quality, and support by maintaining influence over, and active involvement in, the subcontractor's quality system. As such, the subcontractor's facility is considered to be a manufacturing site for the approval holder.

Subcontractor Relationship Responsibilities

The approval documentation on file at NIOSH must demonstrate that the following criteria have been met for NIOSH recognition of a subcontractor.

- a. As with all other NIOSH approvals, the approval holder maintains responsibility for all aspects of the approval: control over product drawings, material specifications, parts lists, and manufacturing processes; control over the requirements for final inspection and testing; and approval of any changes to the above.
- b. The approval holder must assure that a subcontractor has demonstrated the ability to supply product that consistently meets the established release criteria, and has adequate quality systems and procedures in place to assure product quality on an ongoing basis.
- c. The approval holder must establish and maintain active involvement and influence over subcontractor quality systems. This can be demonstrated in many different ways. One example of this involvement and influence can be exhibited by participating in the subcontractor's management reviews (as defined by ISO 9001, 2000, section 5.6) required by the subcontractor's Quality System. A second example is participation in the subcontractor's Material Review Board.
- d. The approval holder's methods for maintaining active involvement and influence over their subcontractor's quality system needs to be documented in a plan or procedure that suits the individual situation and manufacturing complexity of the secured goods. This plan or procedure must be formally submitted to NIOSH.
- e. The approval holder will maintain copies of subcontractor quality records that demonstrate compliance with NIOSH performance requirements. It is important to assure that, in the event of a broken relationship, both the Approval Holder and NIOSH have continued access to those records.
- f. All submissions related to the approval must be made by an authorized representative of the approval holder. The subcontractor's Quality Manual and related quality system documents must represent how the approval holder establishes and maintains active involvement and influence over the subcontractor's quality system. This information must be specifically indicated and documented as part of a Quality Assurance Application. As with all Quality Manuals, a process must be established and followed for ongoing resubmission of the Quality Manual and related quality system documents in the event of significant changes, and on a periodic basis, per NIOSH requirements.
- g. All subcontractor relationships must be listed as an approval holder's manufacturing site, with a designated point of contact, on the NIOSH Standard Application Form (SAF) for direct shipment from the subcontractor to be acceptable under the NIOSH Approval.

- h. All manufacturing sites for NIOSH-approved products, including subcontractor facilities, will be audited by NIOSH on a regular basis. The Institute will not contact the subcontractor directly, but will always work through the approval holder's designated representative for the specific manufacturing site.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Heinz W. Ahlers". The signature is fluid and cursive, with the first name "Heinz" being more prominent.

Heinz W. Ahlers
Acting Branch Chief
Respirator Branch
National Personal Protective Technology Laboratory

